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(71) Applicant: **UNIVERSITY OF PITTSBURGH** [US/US]; 200 Gardener Steel Conference Center, Thackeray & O'Hara Streets, Pittsburgh, PA 15260 (US).

(72) Inventors: **ZENATI, Marco**; 104 Hawthorne Road, Pittsburgh, PA 15238 (US). **SCHWARTZMAN, David, S.**; 6 Georigian Place, Pittsburgh, PA 15215 (US). **GARTNER, Mark, J.**; 127 Oakhaven Drive, Wexford, PA 15090 (US). **McKEEL, Daniel, T.**; 2688 Sunnyfield Drive, Pittsburgh, PA 15241 (US).

(74) Agents: **DOUGHERTY, JR.** et al.; REED SMITH LLP, P.O. Box 488, Pittsburgh, PA 15230-0488 (US).

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(54) Title: DEVICE AND METHOD OF USE FOR FUNCTIONAL ISOLATION OF ANIMAL OR HUMAN TISSUES

(57) Abstract: A method and apparatus for functionally occluding the lumen of the left atrial appendage (LAA) is provided. Access to the LAA is through an epicardial approach. The devices function to capture the LAA through various non-invasive means. After capturing the LAA with the devices and methods provided, a clamping device is preferably disposed about the base of the appendage. In certain embodiments, the appendage remains viable subsequent to the functional occlusion of the lumen.

DEVICE AND METHOD OF USE FOR FUNCTIONAL ISOLATION OF ANIMAL OR HUMAN TISSUES

[1] This application claims the benefit under 35 U.S.C. 119(e) of U.S. Provisional Application No. 60/380,630 filed May 14, 2002.

BACKGROUND

FIELD OF THE INVENTION

[2] Embolic stroke is the nation's third leading killer for adults and a major cause of disability among older Americans. There are over 80,000 strokes per year in the United States alone. A common cause of embolic stroke is thrombus formation in the heart resulting from stagnant blood flow that occurs as a result of atrial fibrillation. Atrial fibrillation ("AF") is an extremely deleterious condition resulting in chaotic cardiac rhythms that typically precipitate lower cardiac output and irregular blood flow in various regions of the heart. There are over five million people worldwide with AF and about four hundred thousand new cases reported each year. Patients with AF are at approximately a 500 percent greater risk of embolic stroke due to the condition. Though pharmacologic treatments of AF are common, they are palliative rather than curative. Furthermore, a patient with AF commonly experiences a significantly decreased quality of life due, in large part, to the fear of a stroke and lifestyle restrictions associated with the attendant pharmaceutical regimen.

[3] Patients with AF often develop thrombus in the left atrial appendage (LAA) of the heart. The LAA is a protrusion which looks like a small finger or windsock extending from the lateral wall of the left atrium between the mitral valve and root of the left pulmonary vein. The interior of the LAA is open to the left atrium allowing blood to flow from the left atrium into the appendage. The physiological function of the LAA is not fully understood. However it is known to be highly innervated indicating that it may have some neurological role. The LAA is also

known to secrete substances leading to various theories of its endocrine and/or paracrine nature. Further, the LAA may function as a physical compliance chamber for the left atrium.

[4] The LAA normally contracts with the rest of the left atrium when a heart is in a normal cardiac cycle thus keeping blood from becoming stagnant therein. But, in patients with AF, the LAA often fails to contract with any vigor or synchronicity as the result of chaotic electrical signals resulting from the pathology associated with AF. As a result, thrombus formation is predisposed to form in the stagnant blood within the LAA. Should any thromboembolic particles of this "clot" dislodge and travel to the brain, stroke occurs. Furthermore, the LAA has been demonstrated as a focal region for generation of the abnormal cardiac electrical signals causing AF. Thus, functional or electrical isolation, or both, is necessary to prevent the deleterious consequences associated with LAA pathologies secondary to AF.

[5] Blackshear and Odell have reported that of the 1288 patients with non-rheumatic atrial fibrillation involved in their study, 221 (17%) had thrombus detected in the left atrium of the heart. Blackshear JL, Odell JA. *Appendage obliteration to reduce stroke in cardiac surgical patients with atrial fibrillation.* Ann Thorac. Surg., 1996.61(2):755-9. Of the patients with atrial thrombus, 201 (91%) had the atrial thrombus located within the left atrial appendage. The foregoing suggests that the elimination or containment of thrombus formed within the LAA of patients with atrial fibrillation would significantly reduce the incidence of stroke in those patients.

[6] Pharmacological therapies for stroke prevention, such as oral or systemic administration of Warfarin or the like, are complicated by serious side effects of the medications, and patient pharmacologic noncompliance. While the most effective current palliative pharmacologic therapy for AF is Warfarin, this therapy is contraindicated in many patients, particularly the elderly in whom the risk of stroke is the highest. These issues suggest that a proactive curative local approach may be

better suited to treat AF–related stroke, in contrast to a reactive palliative systemic approach.

[7] Direct surgical and thorascopic techniques have been used to obliterate the LAA. Nonetheless, many patients are unsuitable candidates for such surgical procedures due to a compromised condition (*e.g.* mitral valve disease) or those having previously undergone cardiac surgery. Furthermore, the perceived risks of even thorascopic surgical procedures often outweigh the potential benefits of this treatment modality. See Blackshear and Odell above. See also Lindsay BD. *Obliteration of the left atrial appendage: A concept worth testing.* Ann Thorac. Surg., 1996.61(2):515.

[8] Minimally invasive endovascular procedures and devices have been proposed in response to the perceived risks associated with traditional surgical procedures to address isolation or obliteration of the LAA. See, for example, U.S. Patent No. 6,231,561 by Frazier et al. entitled "Method and Apparatus for Closing a Body Lumen" (the '561 patent). There are several problems with approaching the left atrial appendage with an endovascular catheter as shown in the '561 patent. For example, access to the left atrium is complicated and requires transeptal puncture between the right atrium and left atrium to access the LAA. This approach risks blood shunting and dislodgment of existing thrombus. Further, the endoscopic devices of the '561 patent require tissue anchors be placed into tissue being closed. The invasion of the endocardium in this manner when closing the LAA, for example, is traumatic to the tissue. Further, there are attendant inherent risks with any procedure that requires endovascular entry into the circulatory system with a medical device, such as systemic infection.

[9] What has been needed is a less invasive atraumatic method and device for isolating, excluding, closing or occluding a target tissue, body lumen or appendage. Specifically, it would be desirable to provide an epicardial device and method for

containment or elimination of thrombus formation in the LAA of patients with atrial fibrillation. The present invention satisfies these and other needs.

SUMMARY OF THE INVENTION

[10] Accordingly, the present invention is directed to devices and methods to capture and isolate tissue. More particularly, this invention relates to devices and methods for selectively capturing, manipulating and isolating, excluding, occluding or ablating a target tissue, lumen or appendage using mechanical, electrical, radiative, chemical, or thermal energies. Preferably, the isolation, exclusion, occlusion or ablation results from a minimally invasive, external action upon the target tissue. For example, if the left atrial appendage were the target, isolation would be accomplished, in accordance with the present invention, by means of pericardial approach, gentle, non-invasive capture of the epicardial surface of the appendage (i.e. the epicardial surface is not penetrated), followed by subsequent isolation. Similarly, if the target tissue is the colonic appendage, the appendage would be accessed, in accordance with the present invention, via peritoneal approach, non-penetrating capture of the serosal surface and subsequent isolation, for example, by any of the various means discussed further below.

[11] A further aspect of the present invention is directed to devices and methods for functional isolation of tissue, by mechanical and/or electrical, radiative, chemical, or thermal means. Particularly, isolation of the left atrial appendage (LAA), preferably by external/epicardial capture, manipulation, stabilization, and attachment of a closure device to the base of the LAA. One purpose of mechanically occluding the orifice between the LAA and the left atrium is to prevent formation within, or passage of embolic material from, the LAA into the left atrium and hence, into the bloodstream of a patient. Entry of these emboli into the patient's blood stream can have deleterious consequences including cerebral stroke.

[12] There is provided in accordance with one aspect of the invention, an apparatus having a capture chamber that substantially encompasses the target tissue, lumen, or appendage. The capture chamber can take a variety of forms depending on the type of medical procedure and surgical approach undertaken. For example, in a conventional open chest procedure to isolate the LAA, the capture chamber may be of fixed construction (*e.g.*, non-collapsible or rigid) and may be connected directly to a source of negative pressure. Alternately, if a minimally invasive, (*i.e.* closed-chest) procedure is undertaken to isolate the LAA, the capture chamber may be provided in a collapsed state for subsequent deployment when it is adjacent to the LAA. In the collapsed embodiment, it is preferable for the chamber to be connected to the distal end of an extension to facilitate placement, and to a source of negative pressure for fixation of the device to the epicardial tissue.

[13] Apart from the structural characteristics of the capture chamber (*e.g.* collapsible or non-collapsible), the chamber will preferably contain an intake port and an aspiration port. The intake port will preferably contain a flexible cup-like structure disposed around the interior perimeter of the rim of the opening. The cup-like structure is preferable oriented in a convex manner relative to the interior of the capture chamber. The inner rim of the intake port is preferably comprised of a spring-reinforced soft polymeric material that allows gentle passage of the target tissue or appendage into the chamber and facilitates a seal between the port and the surface of the target tissue. Alternately, the intake port of the capture chamber may itself be a flexible cup-like structure.

[14] In a procedure to isolate the LAA, the intake port preferably has a transverse dimension and shape sufficient to accommodate the patient's LAA. The volume of the lumen of the LAA, along with the orifice between the LAA and the left atrium, can vary remarkably. It has been reported that dimensions of the human LAA range in volume from 0.7 ml to 19.2 ml, and that the orifice's minimum opening ranged from 5 to 27 mm and a maximum diameter from 10 to 40 mm. Furthermore, the length of the LAA was reported as ranging from 17 mm to 51 mm. Therefore, a capture chamber having an intake port constructed in accordance with this invention will range in size, shape, volume and dimension to accommodate each of the above ranges, as well as other size/capacity restrictions known to one skilled in the art.

[15] The intake port is preferably configured to sealingly engage the epicardial surface of a patient's heart. Upon the application of a negative pressure (*i.e.*, a vacuum) to the chamber, (*e.g.* via an aspiration port) the structure around the intake port suctionally engages the epicardial surface of the heart and preferably proceeds to achieve a seal around the base of the appendage, thus stabilizing the structure for further manipulation. The aspiration port is preferably connected via a connecting tube to a source of adjustable negative pressure that is under the control of the physician to further facilitate capture, manipulation and release of the target tissue.

[16] In all of the capture devices and methods of the present invention, it is preferable to accomplish the capturing step without adversely impacting the patient. For example, when using the capture chamber (described above) or the texture pins (described below) to capture the LAA, it is preferable to achieve capture and stabilization of the appendage without expelling any embolic material contained within its lumen.

[17] The capture chambers of the present invention may further include an integral clamping device or clamping means that can be deployed around the base of the LAA while the appendage is within the capture chamber. The clamping device or means may include metallic, polymeric, or biodegradable jaws, of various surface textures and geometries, to engage the outer periphery of the appendage being isolated or occluded. The clamping device (or means) serves to atraumatically or traumatically secure or restrict the outer periphery of the surface of the base of the left atrial appendage so as to prevent the passage of embolic material or other materials through an inner passageway. The clamping means will typically be a structure comprised of a material with appropriate biocompatibility, mechanical, electrical, thermal or radiative characteristics, depending upon the application. Typical examples of suitable materials for the clamping device (or means) include titanium, medical-grade stainless steel, or various known polymeric compounds, for example, high-density polypropylene, or poly-l-lactic acid (PLLA)-, polyglycolic acid-, polycaprolactone-, polyorthoesther-based compounds.

[18] In an alternate embodiment, a device having features of the invention will include a pair of moveable textured pins for capturing, manipulating and mechanically and/or

electrically occluding the LAA. The pins are preferably configured to atraumatically engage, position and stabilize the epicardial surface of the LAA. For example, the pins may start in close parallel relation to one another and be capable of lateral planar separation. In this way, the pins can be separated to create a gap or opening of an appropriate size to receive or capture the LAA. Each of these pins are preferably capable of independent axial rotation.

[19] It is most preferable if the pins are capable of a wide-range of spatial orientation and movement to facilitate capture of the LAA. Once separated by the appropriate distance, the textured pins preferably rotate to "draw-in" the appendage. For example, one pin may rotate in a clockwise direction and the other may rotate in a counter-clockwise direction. Alternately, the pins may move independently – such that one pin remains fixed while the other rotates. Additionally, it is preferable if the pin-holder device is itself axially rotatable to allow one pin to sweep an arc relative to the other pin. In all spatial orientations, it is preferable if the pins remain in parallel relation relative to one another.

[20] Once the pins are positioned at the base of the LAA, they may be moved together in a lateral planar direction to decrease the distance between the pins and thereby secure and maintain the position of the LAA. These pins may then be irremovably engaged to one another to form a clamping device which will be disengaged from the apparatus and remain securely in place at the base of the LAA. Alternatively, a separate clamp would be positioned and secured at the base of the LAA. This clamp would thereby occlude the passage of embolic material from the lumen of the LAA to the chamber of the left atrium.

[21] In an alternate absorbable embodiment, the clamp may be used to initiate an inflammation response via the imposition of mechanical or other stress upon the tissue. Healing that occurs as a result of this imposed wound will mechanically occlude the orifice of the LAA to prevent passage of blood and/or emboli between the appendage and the heart chamber. This absorbable clamp would preferably

remain securely in place during the temporal period of healing and then subsequently dissolve.

[22] Another aspect of the present invention includes the electrical isolation of the LAA to prevent conduction of the chaotic electrical signals that originate in the LAA to other areas of the heart. Devices constructed in accordance with the invention are usable in either traditional or minimally invasive surgical approaches. An endoscopic-based epicardial approach to LAA isolation provides several advantages over both transluminal vascular catheterization and traditional surgical techniques such as thoracotomy or median sternotomy.

[23] Because of the role the LAA plays in hormone production, a method of isolating the lumen to prevent emboli from forming or exiting the LAA, while maintaining vascularization of the appendage myocardium, is also provided.

[24] In addition to physical isolation via mechanical means, it is also desirable to achieve electrical isolation because of the role that the LAA may play in the pathogenesis of AF. For example, since the LAA is a focus of disruptive electrical activity that may contribute to the pathogenesis AF, it would be desirable to isolate this activity. One means of achieving electrical isolation is to create a lesion using a combination of mechanical, electrical or thermal energy, to prevent the disruptive electrical signals from propagating to other areas of the heart.

[25] Bipolar electrodes have achieved wide acceptance by surgeons for a variety of electrosurgical procedures. Electrosurgical techniques are generally divided into two classes, namely monopolar techniques and bipolar techniques. In monopolar procedures, the electric current flux of the active electrode passes through the patient's body to the return electrode. In bipolar procedures, the electromagnetic wave flows from an active electrode to another active electrode through a limited amount of tissue between the two electrodes.

[26] Modern electrosurgical equipment produces an electromagnetic wave of a very high frequency that reaches between 350,000 cps (cycles/second or 350 kilohertz) and 4,000,000 cps (4 MHz - megahertz). The wave used in electrosurgeries is in the mean of the frequency used in the FM radio, and thus, electrosurgical waves are frequently called radiofrequency (RF) waves. Because bipolar electrodes provide for the passage of electromagnetic energy between two (2) active electrodes in a directionally controllable manner, it is possible to use higher frequency energy because it can be directed. Consequently, the loss of energy that radiates to un-targeted areas (such as tissue surrounding the target site) is minimized through the use of bipolar electrodes.

[27] The three main effects caused by radio frequency waves passing through biologic tissues are the Faradic effect, the electrolytic effect and the thermal effect. The Faradic effect is not usually observed with modern electrosurgical equipment that can achieve frequencies above 300 kHz. The electrolytic effect is caused by the polarization of ions in a tissue. When an alternating current is applied to a tissue composed mainly of water and electrolytes, the ionized particles in the tissue will vibrate, thereby increasing kinetic energy. Due to the high frequency applied through the alternating current, the ionized particles will move only slightly, but the kinetic energy will ultimately lead to a temperature increase in the tissue.

[28] There are several factors that influence the mode of conduction of heat through a tissue (i.e. the thermal effect). Water is an excellent medium to maintain thermal balance in a tissue because of its constant vaporization temperature. Another important factor is the vasculature of the tissue, since circulation helps dissipation of heat. Thus the effects caused by a temperature rise in biologic tissue will depend both on the final temperature that is reached and the total duration an elevated temperature is maintained. When the temperature rises slowly, the tissue will dry out and there will be coagulation of constitutive proteins. In contrast, when the tissue is quickly heated to high temperatures neither vaporization or thermal

transference will effectively dissipate heat, and therefore, tissue temperatures will rise above 100 °C. Intracellular water vaporization will produce a volume increase and subsequent cell membrane rupture due to excessive internal pressure. Several factors, including water content, will influence the electrical resistance of tissues. The electrical resistance of dry tissue is much higher than that of well hydrated tissue. It may be preferable to employ a conductive fluid, such as saline, during application of the RF energy.

[29] The bipolar electrodes of the present invention are preferably incorporated into the rotatable pins of the device. This allows the LAA to be captured, positioned, and electrically isolated using a single device and in a single operational step. Control of a device having biopolar electrodes may be accomplished, for example, by the circuitry and teaching found in U.S. Patent No. 6,203,541 to Keppel ("the '541 patent"), which is incorporated herein by reference for these teachings. Further, the electrodes are preferably connected through the central circuitry to an external radio frequency power supply.

[30] In addition to the various closure means presented herein, an embodiment of a closure device having a pharmacological agent associated with the surface thereof is also contemplated. For example, U.S. Patent No. 5,282,844 discloses steroid eluting electrodes, and is incorporated herein by reference for this teaching.

[31] An additional embodiment includes the use of an integrated system to effectively visualize the LAA or other tissues to be closed. Endoscopes have been used for many years in the medical field for viewing within a desired region of the patient's body through the patient's airway, other natural orifices, or a surgical incision. An endoscope typically has an elongated flexible probe fixed to a housing at its proximal end. Additionally, an endoscope may have a medical device or assembly attached to its distal end for carrying out a specific procedure or function. Optical fibers typically extend the length of the endoscopic probe and carry an image from the distal end of the probe to the housing, where it can be viewed through an eye

piece by the physician. The housing generally includes one or more controls allowing the physician to direct the distal tip of the probe in a desired direction. The probe can also be equipped with one or more instrument channels for surgical implements. Additionally, a suction channel normally extends the length of the endoscopic probe to facilitate removal of mucus, blood, or secretions that can obstruct the physician's view or interfere with endoscopic surgery.

[32] There is provided in accordance with one aspect of the present invention, an endoscopic device for functionally isolating the left atrial appendage from fluid and electrical communication with the left atrium of a patient while maintaining the capillary blood flow carrying hormone produced in the LAA tissue. It is contemplated that by using the devices and methods in accordance with the present invention, following the occlusion of the orifice of the LAA, the appendage can optionally remain viable. Viability is defined as capillary blood flow to the myocardium and hormonal exchange between the appendage and surrounding tissue. It is most preferable if the lumen of the LAA can be isolated with the endoscopic devices of the present invention without destroying the vascularization of the tissue of the appendage.

[33] Generally, an endoscopic device in accordance with the present invention will include an elongated extension having a proximal and distal end. The proximal end of the extension preferably contains a controller unit that can manipulate and implement an assembly located at the distal end of the extension. Preferably, the extension will include optical fibers extending its length to carry a visual image from the distal end of the extension for viewing and to assist the physician in manipulating the assembly at the distal end. Preferably, the assembly can capture, stabilize, and (mechanically and/or electrically) isolate the LAA. This isolation process may be accomplished, for example, by way of a capture chamber or via a textured pin-based clamping device as described previously herein. The endoscopic device integrated with the capture devices of the present invention and the methods

of the present invention, are applicable to a variety of surgical procedures and approaches for isolation of animal and human tissues, lumens, or appendages.

[34] In accordance with a further aspect of the present invention, there is provided an endoscopic device for occluding the left atrial appendage (LAA) of a patient. The device is comprised of a probe-extension with a controller at its proximal end to allow spatial manipulation of a distal assembly. The controller is preferably operable wherein initiation of an action upon a trigger or switch of the controller will cause a corresponding reaction to an assembly or component attached to the distal end of the probe/extension. For example, operation of a trigger at the proximal end of the probe may facilitate placement or deployment of a collapsible capture chamber, or alternatively, separate a pair of rotatable pins in a lateral co-planar direction. Additional switches/triggers may generate suction controls, rotation controls and/or light sources, as well as deploy clamping devices or disengage the removable pin-clamp assembly.

[35] In accordance with a further aspect of the present invention, there is provided a method of mechanically isolating the orifice of the left atrial appendage. The method comprises the steps of accessing the LAA, capturing the LAA and attaching a closure device to the base of the LAA. Access to the LAA is preferably epicardial access, either through open-chest or minimally invasive approaches.

[36] A method is provided of electrically isolating the tissue of the left atrial appendage in accordance with a further aspect of the present invention. The method comprises the steps of accessing the LAA, capturing the LAA, and transmitting an electrical, thermal, or mechanical energy of sufficient amplitude and duration to create a transmural lesion to isolate the LAA tissue. Access to the LAA is preferably epicardial access, either through open-chest or minimally invasive approaches.

[37] The step of electrically isolating a body appendage, for example the colonic appendage, may comprise peritoneal introduction of a device into the abdomen,

positioning the capture assembly adjacent the appendage; capturing the appendage; positioning the bipolar electrodes adjacent the target; and applying sufficient RF energy to the bipolar electrodes to isolate, exclude, occlude or ablate the appendage.

[38] Preferably, the capturing step comprises non-invasively securing the appendage within a capture chamber through the use of suction. In an alternate embodiment, the appendage may be gently captured with rotating textured pins that are separable and act to draw in the appendage by rotation of these textured pins.

[39] The closure devices to be used in accordance with the methods of the present invention may include sutureless clamps that provide closure via bilateral or circumferential pressure. For example, a bilateral clamp constructed of appropriate biomaterial may be applied at the base of the LAA to "squeeze" the opening closed simultaneously imposing a mechanical stress to initiate a healing response. After the orifice of the LAA has healed shut the biomaterial-based clamp harmlessly dissolves. Alternately, a substantially circular clamping device may be employed to ensnare the appendage and close the opening by compressing the periphery of the base of the appendage while still permitting capillary blood flow to the LAA for hormone exchange.

[40] The step of deploying the clamping device is preferably accomplished after capturing and stabilizing the base of the LAA using a separate or integral extension device. For example, the device and methods of U.S. Patent 5,984,917 to Fleischman et. al., would be readily adaptable to the present invention. In practicing the methods of this invention, the clamp is preferably positioned at the base of the LAA and engaged to compress the base of the LAA in a secure and permanent manner. Additionally, a feedback mechanism and/or sensor associated with the clamp may preferably provide the surgeon with an indication of the amount of mechanical force applied by the clamp to allow tailoring to a particular degree of functional isolation. For example, piezoelectric crystals or another strain gauge device could be embedded into the rotatable pins such that material stress as a result

of applied force causes a voltage potential. This voltage potential would be proportional to the amount of applied force and could be transduced from the apparatus for display to the physician using vibration, sound, or visual methodologies. After proper deployment, the clamp may preferably be detached from the extension device and remain securely in place.

BRIEF DESCRIPTION OF THE DRAWINGS

[41] For the present invention to be clearly understood and readily practiced, it will be further described in conjunction with the following figures, wherein like reference characters designate the same or similar elements, and which figures are incorporated into and constitute a part of the specification, wherein:

[42] **Figure 1** is an anterior illustration of a heart with the proximal parts of the great vessels.

[43] **Figure 2** is a schematic cross-sectional view of the left atrial appendage (LAA).

[44] **Figure 3** is a perspective view of a device having a non-collapsible capture chamber in accordance with one embodiment of the invention.

[45] **Figure 4** is a schematic cross-sectional view of the left atrial appendage captured within a non-collapsible capture chamber of a device in accordance with one embodiment of the invention.

[46] **Figure 5A** is a perspective view of a medical device having a collapsible capture chamber in accordance with one embodiment of the invention.

[47] **Figure 5B** is a perspective view of a stowed collapsible capture chamber prior to deployment.

[48] **Figures 6 A-F** are a series of schematic illustrations showing one method of operation of the medical device shown in **Fig. 5**.

[49] **Figure 7** is a perspective view of a medical device in accordance with one embodiment of the invention.

[50] **Figures 8 A-B** are perspective views and schematic illustrations of an assembly for the epicardial capture, stabilization and isolation of the LAA in accordance with one embodiment of the invention.

[51] **Figures 9 A-C** are a series of illustrations showing the operation and articulation of a device in accordance with one embodiment of the invention.

[52] **Figure 10** is a schematic cross-sectional view of the LAA showing the textured pin placement of a capture device as shown in **Fig. 7**, prior to deployment of the pins and subsequent capture of the LAA.

[53] **Figures 11A-D** are schematic representations showing the capture and isolation of the lumen of the LAA by a device equipped with the assembly shown in **Fig. 7**.

[54] **Figures 12 A-B** are schematic cross-sectional representations showing the pins of the device of **Fig. 7** fully deployed (A) at the base of the LAA and subsequently clamped (B) thereby isolating the lumen of the LAA from the left atrium.

[55] **Figures 13 A-B** are schematic cross-sectional representations showing the pins of the device of **Fig. 7** fully deployed (A) and being placed adjacent the base of the LAA by one pin sweeping an arc about the other pin, and subsequently clamped (B) thereby isolating the lumen of the LAA from the left atrium.

DETAILED DESCRIPTION OF THE INVENTION

[56] It is to be understood that the figures and descriptions of the present invention have been simplified to illustrate elements that are relevant for a clear understanding of the invention, while eliminating, for purposes of clarity, other elements that may be well known. Those of ordinary skill in the art will recognize that other elements are desirable and/or required in order to implement the present invention. However,

because such elements are either well known or well within the skill of the art, and because they do not facilitate a better understanding of the present invention, a discussion of such elements is not provided herein. The detailed description will be provided hereinbelow with reference to the attached drawings.

[57] Referring to **Fig. 1**, a heart **10** is illustrated to show certain portions including the left ventricle **12**, the left atrium **14**, the left atrial appendage (LAA) **16**, the pulmonary artery **18**, the aorta **20**, the right ventricle **22**, the right atrium **24**, and the right atrial appendage **26**. As is understood in the art, the left atrium **14** is located above the left ventricle **12** and the two are separated by the mitral valve (not illustrated). The LAA **16** is normally in fluid and electrical communication with the left atrium **14** such that blood flows in and out of the LAA, and electrical impulses conduct to and from the LAA **16** as the heart **10** beats.

[58] **Fig. 2** is a schematic cross section of the LAA **16**. The chamber of the left atrium **30** and the lumen **32** of the LAA **16** are shown in communication via orifice **34**. The LAA is further defined as having a base portion **36** proximal to its attachment with the epicardial surface of the left atrium **30**, and a body portion **38** distal to the point of attachment of the appendage **16** with the left atrium. The walls **40** of the LAA **16** are vascularized heart tissue substantially similar to the walls **42** of the left atrium.

[59] **Fig. 3** is a perspective view of one type of capture chamber device **40** contemplated by the present invention. The device is generally comprised of a vacuum source **44** attached to a capture chamber **50**. In the embodiment shown in **Fig. 3**, the capture chamber **50** is rigid (*i.e.* non-collapsible) in construction, but collapsible and/or deployable chambers are also contemplated, as more fully described below.

[60] The capture chamber **50** is shown with an intake port **46** having a flexible cup-like structure **48** disposed around the periphery of the port **46** opening. The chamber **50** is also equipped with an aspiration port **47** that connects to the vacuum source **44**.

Preferably, the aspiration port **47** is located on an opposite axis relative to the intake port **46**.

[61] Generally, the device **40** is used such that upon positioning the intake port **46** of the capture chamber **50** adjacent the LAA of a patient, a vacuum is applied to the aspiration port **47** causing the LAA to enter the chamber **50** via the intake port **46**, as shown and discussed further below with reference to **Fig. 4**.

[62] **Fig. 4** illustrates a schematic cross section of one embodiment of the invention. The device shown is for attachment to the distal end of a medical device and includes a capture chamber **50** for capturing and stabilizing and/or immobilizing a target tissue, which in this example is the LAA **16**. In the embodiment shown, the LAA **16** enters the chamber **50** via an intake port **46**, for example, by being drawn into the chamber **50**, when a vacuum is applied to the aspiration port (not shown) of the chamber **50**. The intake port **46** is preferably comprised of a flexible structure **48** which acts to secure the base **36** of the LAA **16** without penetrating the epicardial surface of the LAA **16** and without causing emboli **51** to be expelled from the LAA cavity into the left atrium. This non-invasive, gentle-capture method preferably secures and stabilizes the LAA **16** for further procedures and manipulation, such as the attachment of a clamping or closure device (not shown in Fig. 4) to the base **36** of the LAA, as described further herein. Preferably, the intake port **46** is generally circular in shape and is a ring-like structure having a diameter of less than 50 mm.

[63] **Figure 5A** shows a further embodiment of a medical device **100** having a capture chamber **150** as contemplated by the present invention. The medical device **100** includes an elongated shaft **110** comprised of a hollow sheath **112** and having proximal **120** and distal **130** ends. At the proximal end **120**, controllers and connections are preferably provided to allow for manipulation of the various components of the device provided at the distal end. Communication between the control mechanisms at the proximal end **120** and the components located at the distal end **130** of the device **100** may be accomplished by cables, pushrods **114**,

connecting tubes **118**, or any other means capable of placing the distal-end component under the control of a surgeon at the proximal end. These means of communication (**114, 118**) between the proximal **120** and distal **130** ends of the device **100,** may be located within the sheath **112** or adjacent to the sheath **112,** such as is shown for connecting tube **118**. A connector **122** for a vacuum source is preferably provided at the proximal end **120**, such that the vacuum source is in operable connection with a collapsible capture chamber **150** at the distal end **130** of the device **100**.

[64] A complete device **100** further includes a deployable occlusion snare (i.e. closure device) **134** to encircle the base of the LAA. The occlusion snare **134** may be comprised of any suitable material, and it is preferable if, following deployment around the base of the appendage and constriction (as discussed below with reference to **Fig. 6F**), the snare is easily separable from the actuator **132**. Prior to insertion of the medical device **100**, it is preferable if the components at the distal end **130** of the device **100** can be "stowed" within cannula **160** for insertion through an endoscopic port, for example, as shown in **Fig. 5B**.

[65] Preferably, methods of using the device **100** are by means of a sub-xyphoid pericardial access including procedures that are conducted under local anesthetic. Pericardial access without effusion has been achieved by various methodologies including sub-xiphoid access using the PerDUCER™ device from Comedicus Inc. (Columbia Heights, Minnesota). In using the PerDUCER™ device, a stab incision is made in the sub-xyphoid area and a 17-gauge angled cannula with a preloaded guide wire is advanced into the mediastinal space. After cannula removal, a 19 Fr. is inserted over the wire and the PerDUCER™ device is positioned such that an isolated portion of pericardium is captured by suction. A sheathed needle is then advanced which punctures this isolation portion allowing pericardial access. A similar access methodology for deployment of the proposed devices of this invention are contemplated.

[66] With further reference to **Fig. 5A**, the collapsible chamber **150** is preferably made out of flexible polyurethane-type material. The chamber **150** is also equipped with an aspiration port **47** that connects to the vacuum source . Preferably, the aspiration port **47** is located on an opposite axis relative to the intake port **46**. When fully deployed, the intake port **46** of the collapsible chamber **150** may range between 10 and 40 mm, preferably between 12 and 30 mm, and most preferably between 16 and 22 mm. The opening may further be comprised of a rim **152** of nitinol wire, or other similar material, to maintain the position of the opening for deployment.

[67] A rotatable knob **124** is also provided in operable connection with a clamp actuator **132** such that, for example, when the knob **124** is rotated in a clockwise direction, the clamp **134** at the distal end **130** of the device **100** is drawn closed, as further shown in **Fig. 6E.** Similarly when the knob **124** is rotated in a counter-clockwise direction, the clamp **134** is released from the actuator **132.**

[68] With reference to **Figs. 6 A-F**, the device **100** of **Fig. 5** and a method of its use are further illustrated. **Fig. 6A** is a schematic sideview showing the collapsible capture chamber **150**/closure device **134** assembly approaching the LAA **16** for initial capture of the appendage. Upon the capture chamber **150** coming into proximity with the appendage **16**, a vacuum is applied to the connecting line **124** such that the collapsible chamber **150** conforms to the appendage **16** and allows the chamber **150** to be suctioned over the appendage **16** as the device proceeds to be advanced, as shown in **Figs. 6B** and **6C**. Once the appendage **16** has been fully captured in the collapsible chamber **150 (Fig. 6C)**, the appendage **16** can be further manipulated and isolated. For example, as shown in **Fig. 6D**, the appendage **16** can be manipulated (withdrawn) from the circumference of the closure device **134**, wherein, upon this re-positioning, the closure device **134** can be drawn together around the base **36** of the appendage **16**, as previously described and as shown in **Fig. 6E**. After clamping the base **36** of the appendage **16** to isolate its contents, the vacuum being supplied by connecting line **124** can be decreased or discontinued and

the collapsible chamber **150** attached to the device (not shown) can be withdrawn, as shown in **Fig. 6F**.

[69] **Fig. 7** shows a medical device in accordance with another preferred embodiment of the present invention. The device **70** is comprised of an extension **72** having a proximal end **74** and a distal end **76**. The extension **72** may be a flexible wire **77** contained within a bendable sheath, for example, or a preferably stiffened hollow sheath with little or no flex. This sheath is movable once the LAA or similar tissue is captured to facilitate the distal assembly **60** to move with the tissue. The device **70** further includes a rigid clamp beam **78** that functions to stabilize the flexible extension **72** during insertion into the patient and subsequent capture and stabilization of the target tissue. Following insertion of the device **70** into the patient, the clamp beam **78** may be removed such that the flexible extension **72** and pin holder **62** can move independently to allow maximum surgical flexibility and control. The assembly **60** as shown in **Fig. 8** is one embodiment that is preferably comprised of a pin holder **62**, having sub-components such as a textured first pin **64** and a textured second pin **66**. Alternatively, the assembly **60** may be of a type and design comprised of a capture chamber as previously shown in **Figs. 3** or **5**, for example.

[70] **Fig. 8A** shows another embodiment of an assembly **60** for attachment to the distal end of a surgical instrument. The assembly **60** is comprised of a pin holder **62**, a first textured pin **64** and a second textured pin **66**. The pin holder **62** is preferably capable of axial rotation and is moveable in a plane transverse to the longitudinal axis of the shaft **52**. The pins **64, 66** are held by the pin holder **62** in a substantially parallel relationship along their longitudinal axis relative to each other. In this view, the sub-components of the pin holder **62** (*e.g.*, the pins **64, 66**) are shown in an open parallel relation to one another. Pins **64** and **66** are preferably moveable (separable) in a plane perpendicular to their longitudinal axis (*i.e.* lateral planar movement) such that they can be maintained in a closed parallel relation prior to deployment. The

pin holder **62** is preferably attached to the distal end of the shaft **52** by a controllable universal joint **54** which provides for axial rotation as well as transverse planar movement of the pin holder **62**. It is also preferable for pins **64**, **66** to be capable of independent axial rotation.

[71] **Fig. 8B** shows an end view of pins **64**, **66** in two positions. The textured pins **64**, **66** may be inserted into a patient via a surgical port or other surgical access to the LAA, for example, in position "a" and then be subsequently deployed (separated), for example, to position "b" prior to positioning the pins **64**, **66** adjacent the target tissue. Upon completion of the procedure (*e.g.* isolation of the target tissue) and before assembly **60** is removed from the patient, pins **64**, **66** may be returned to position "a". In an alternative embodiment, the pins **64**, **66** may also comprise the closure/clamp device that acts to mechanically and/or electrically functionally isolate the LAA, as discussed further herein.

[72] **Figs. 9 A-C** further illustrate an assembly for isolating a target tissue, body lumen or appendage of a patent in accordance with one aspect of the present invention. The device is comprised of a shaft **72** with a pistol-grip type of controller **80** for example, as shown in **Fig. 7** attached to its proximal end **74.** Any variety of controllers, now known or later developed, are contemplated in conjunction with the present invention. For example, the trigger/control mechanisms contained within the controller may be mechanical, electro-mechanical, servos, robotic, microprocessors or any combination thereof.

[73] The assembly of **Fig. 9A** also includes a pin holder **62** attached to the distal end **76** of the shaft **72**. In this embodiment illustrated in **Fig. 9** and with reference to **Fig. 7**, the pin holder **62** is connected to and under the operable control of the controller **80** such that the pin holder **62** is moveable in a plane transverse to the longitudinal axis of the device **70**. For example, by operator action upon a trigger (*e.g.*, **81**, **83**) the pin holder **62** is preferably moveable between position "c" and position "d" as shown in **Fig. 7**. The process of moving pin holder **62** in a plane transverse to the

longitudinal axis is shown further in **Figs. 9 A-C**. For example, by rotating the device **70** by 90°, the "up-down" transverse movement **69** shown in **Figs. 9 A-B** becomes the "side to side" transverse movement shown in **Fig. 9C.**

[74] The sub-components **64, 66** preferably move (open and close) in a plane perpendicular to the longitudinal axis of the shaft **72**. This lateral planar movement of the pins **64, 66** preferably can occur in a bilateral sense such that the pins can open or close simultaneously to alter the distance between the pins **64, 66**. Alternately, the pins may operate unilaterally.

[75] One method of using the assembly **60** to capture , for example, the LAA, is for the surgeon to obtain epicardial access to the heart and locate the pins **64, 66** in perpendicular relation to the appendage **16**, as shown, for example, beginning in **Fig. 10**. The pins **64, 66** could subsequently be deployed to an "open" position (for example as previously shown as position "b" in **Fig. 8B** through operation of a controller device). Once deployed, the surgeon would continue to operate a controller (as previously described) to rotate the textured pins **64, 66** in a manner that would cause the pins **64, 66** to progress along the surface of the LAA **16** (or for the appendage to be "drawn-in" to the opening between the pins) as shown, for example, in **Figs. 11A-11C**. Once the pins **64, 66** have been positioned at the base **36** of the LAA **16** (as show in **Fig. 11C**), the pins **64, 66** move back towards one another (*i.e.* lateral planar movement) to close-off the orifice **34** of the LAA **16** as show in **Fig. 11D**. Once the orifice **34** has been closed, a clamp (not shown) may be deployed about the base **36** of the LAA. Alternately, the pins **64, 66** may be electrodes capable of transmitting a bipolar radio frequency. It is preferable if the energy transmitted is of sufficient amplitude and duration to cause the base of the LAA **36** to form a lesion and thereby fuse the orifice closed to isolate the lumen **32** of the LAA, as shown in **Fig. 11D**.

[76] Alternatively, the pins **64, 66** may be "opened" prior to positioning the assembly around the LAA **16**. In that case, the surgeon may be able to place the pins **64, 66**

directly around the base **36** of the LAA **16**, for example, as shown in **Fig. 12A**. If the pins **64**, **66** cannot be placed directly at the base **36** of the LAA **16**, it is preferable that the pins **64**, **66** are able to sweep an arc relative to one another, as shown for example, in **Figs. 13A** and **B**. **Fig. 13A** shows placement of a first pin **64** adjacent the base **36** of the LAA while the second pin **66** sweeps an arc toward the opposite side of the LAA **16**. **Fig. 13B** shows the preferable position of pins **64**, **66** prior to initiating one of the isolation/exclusion/occlusion methods described herein.

[77] In any alternative, (*i.e.* position and deploy or deploy and position) once the textured pins are positioned at the base **36** of the LAA, the pins **64**, **66** may be drawn together (*i.e.*, changed from position "b" to position "a" as previously shown in **Fig. 8B**) to thereby close-off fluid communication between the lumen **32** of the LAA **16** and the left atrium **30** as shown in **Figs. 11D** and **12B**. In addition, thermal, electrical, or mechanical energy may be transmitted from the textured pins to the epicardial tissue to affect electrical isolation of said tissue. Following the mechanical and/or electrical functional isolation of the LAA **16** from the left atrium **30**, a clamp may be deployed to maintain the isolation of the lumen **32** from the atrium **30**. One alternative is to engage the pins **64**, **66** with one another using a simple mechanism such as end caps (not shown) and detach the textured pins **64**, **66** from the pin holder, leaving the pins **64**, **66** in place to isolate the base **36** of the LAA.

[78] In another preferred embodiment using the devices and methods in accordance with the present invention, following the occlusion of the orifice of the LAA, the appendage remains viable allowing capillary blood flow, and hence hormonal exchange, between the appendage and surrounding tissue. It is most preferable if the lumen of the LAA can be isolated without destroying the vascularization of the tissue of the appendage.

[79] Nothing in the above description of the devices is meant to limit the present invention to any specific materials, geometry, or orientation of elements. Many

part/orientation substitutions are contemplated within the scope of the present invention and will be apparent to those skilled in the art. The embodiments described herein are presented by way of example only and should not be used to limit the scope of the invention.

[80] Although the invention has been described in terms of particular embodiments in an application, one of ordinary skill in the art, in light of the teachings herein, can generate additional embodiments and modifications without departing from the spirit of, or exceeding the scope of, the claimed invention. Accordingly, it is understood that the drawings and the descriptions herein are proffered only to facilitate comprehension of the invention and should not be construed to limit the scope thereof.

WHAT IS CLAIMED IS:

1. An apparatus for isolating the lumen of the left atrial appendage (LAA) from the left atrium of a patient, the apparatus comprising:

   a capture chamber having an intake port, said chamber being of sufficient capacity to substantially encompass the LAA; and

   a closure device.

2. The apparatus of Claim 1 wherein the capture chamber further includes an aspiration port.

3. The apparatus of Claim 2 wherein the aspiration port is located on an opposite axis relative to the intake port.

4. The apparatus of Claim 2 wherein the intake port is comprised of a flexible structure that allows the LAA to be non-invasively secured within the capture chamber upon the application of negative pressure to the aspiration port.

5. The apparatus of Claim 4 wherein the flexible structure is substantially convex in shape relative to the capture chamber.

6. The apparatus of Claim 4 wherein the intake port is substantially circular and has a diameter between 10 mm and 40 mm.

7. The apparatus of Claim 1 wherein the capture chamber is oriented in a collapsed state whereby upon deployment to an open state, the sufficient capacity to substantially encompass the LAA is realized.

8. The apparatus of Claim 1 wherein the closure device is comprised of an electrode capable of transmitting a bipolar radio frequency.

9. The apparatus of Claim 1 wherein the closure device is a clamp comprised of a bio-compatible material selected from the group consisting of titanium, stainless steel polymer, PLLA, polyglycolic acid compounds, polycaprolactone compounds or polyorthoester compounds.

10. The apparatus of Claim 1 wherein the closure device includes a feedback mechanism to indicate the amount of compressive force being applied to the LAA upon deployment.

11. The apparatus of Claim 1 wherein the closure device is deployed from the periphery of the capture chamber.

12. The apparatus of Claim 1 wherein the closure device includes a surface having a pharmacologic agent associated with the surface thereof.

13. The apparatus of Claim 1 wherein the closure device is an occlusion snare.

14. The apparatus of Claim 1 wherein the capture chamber is non-collapsible.

15. An endoscopic device for functionally excluding the left atrial appendage from the left atrium of a patient, the device comprising:

    a shaft having a proximal end and a distal end defining a longitudinal axis;

    a controller attached to the proximal end of the shaft; and

    a pin holder attached at the distal end of the shaft, said pin holder being operably connected to said controller.

16. The device of Claim 15 wherein said pin holder is capable of axial rotation.

17. The device of Claim 15 wherein said controller is operably connected to said pin holder such that a person may initiate a physical action upon the controller and cause at least one sub-component of the pin holder to respond.

18. The device of Claim 16 wherein said pin holder is moveable in a plane transverse to the longitudinal axis.

19. The device of Claim 15 wherein said pin holder comprises a plurality of pins maintained in a substantially parallel relationship to one another throughout operation of said device.

20. The device of Claim 17 wherein said sub-component comprises a pin capable of axial rotation.

21. The device of Claim 17 wherein said sub-component remains parallel with the longitudinal axis of said shaft and moves in a plane perpendicular to the said longitudinal axis.

22. The device of Claim 17 wherein said pin holder can pivot up to 90° relative to the longitudinal axis of the shaft in response to an action upon the controller.

23. The device of Claim 16 wherein said pin holder is under the functional control of said controller, the controller having a triggering mechanism selected from the group consisting of mechanical connections, electro-mechanics, servo connections and robotic connections.

24. The device of Claim 15 wherein said pin holder is attached to the shaft by a controllable universal joint.

25. An assembly for attachment to the distal end of an endoscopic medical device, the assembly being operable to capture and isolate a target tissue, body lumen or appendage of a patient, the assembly comprising:

first and second pins in parallel relationship, each of said pins being rotatably connected to a pin holder.

26. The assembly of Claim 25 wherein said first and second pins are capable of lateral planar movement in response to an operator action.

27. The assembly of Claim 25 wherein said first and second pins are rotatable in response to an operator action.

28. The assembly of Claim 26 wherein said first and second pins are able to sweep an arc relative to one another.

29. The assembly of Claim 25 wherein said first and second pins are detachably connected to said pin holder and detachable in response to an operator action.

30. The assembly of Claim 25 wherein said first and second pins can be drawn together to form a compressive clamp.

31. The assembly of Claim 25 wherein said first and second pins are electrodes capable of transmitting a bipolar radio frequency.

32. A method of occluding the lumen of the left atrial appendage (LAA) from the left atrium of a patient, comprising:

accessing the LAA;

capturing the LAA; and

attaching a closure device to the base of the LAA to functionally isolate the lumen of the LAA from the left atrium.

33. The method according to Claim 32 wherein the step of accessing the LAA comprises epicardial access via an endoscopic port.

34. The method according to Claim 32 wherein, following the attaching of a closure device to the base of the LAA, the appendage remains viable.

35. The method according to Claim 32 further comprising dissolution of the closure device.

36. The method according to Claim 32 wherein the step of capturing the LAA is accomplished without penetrating a surface of the appendage.

37. The method according the Claim 32 wherein the closure device functionally isolates the lumen of the LAA by applying bilateral pressure to the base of the LAA.

38. The method according the Claim 32 wherein the closure device functionally isolates the lumen of the LAA by applying circumferential pressure to the base of the LAA.

39. The method according to Claim 32 wherein the step of capturing the LAA comprises suctioning the LAA into a chamber that substantially encompasses the appendage.

40. The method according to Claim 33 wherein the epicardial access is achieved via a direct pericardial puncture via a subxiphoid approach.

41. The method according to Claim 32 wherein the capturing and attaching step are performed by a unitary device.

42. The method according to Claim 41 wherein the unitary device is an endoscope in accordance with Claim 15.

43. A method of performing endoscopic surgery to functionally isolate a target tissue, body lumen or appendage of a patient by restriction of an external surface layer of the tissue, the method comprising:

visualizing the target tissue;

capturing the target tissue by encompassing at least a portion of the external surface layer; and

disposing a closure device adjacent to a portion of the target tissue to isolate the captured target tissue.

44. The method according Claim 43 wherein the visualizing step, the capturing step, and the disposing step are accomplished with a unitary medical device.

45. The method according to Claim 43 wherein the target tissue is the LAA and the closure device prevents the exchange of lumenal contents of the LAA with blood in the left atrium and maintains vascularization of the appendage.

46. A method of constricting the base of the left atrial appendage (LAA) of a patient to functionally close the oriface between the LAA and the left atrium via epicardial access of the patient's heart, the method comprising the steps of:

providing an endoscopic device having capture means and deployment means;

accessing the LAA with the device;

capturing the LAA with the capture means; and

deploying closure means from the device to ensnare the base of the LAA.

47. The method according to Claim 46 wherein the capture means comprises suction immobilization.

48. The method according to Claim 46 wherein the capturing step comprises aspirating the LAA into a chamber.

49. The method of Claim 46 further comprising undertaking the steps of accessing, capturing and deploying under local anesthetic.

50. The method of Claim 46 wherein the steps of accessing, capturing and deploying are performed by a unitary device.

51. The method according to Claim 46 wherein the closure means constricts the base of the LAA to stop blood flow between the lumen of the LAA and the left atrium while allowing the walls of the LAA to remain viable.

52. The method according to Claim 51 wherein the closure means subsequently dissolves.

53. The method according to Claim 46 wherein the closure means are comprised of electrodes, said electrodes capable of transmitting a bipolar radio frequency.

54. The method according to Claim 46 wherein the capture means comprises non-invasive direct contact with the epicardial surface of the LAA.

55. An apparatus for selectively isolating a lumen, the apparatus comprising:

an extension having a proximal end and a distal end and defining a longitudinal axis;

means at the distal end of the extension for non-invasively securing the lumen via contact with the exterior surface of the lumen; and

means at the distal end of the extension for isolating an interior space of said lumen.

56. The apparatus of Claim 55 wherein the extension comprises a shaft having dimensions suitable for introduction into a patient via an endoscopic access port.

57. The apparatus of Claim 55 wherein the non-invasive securing means comprises a capture chamber.

58. The apparatus of Claim 55 wherein the non-invasive securing means and isolating means are comprised of first and second pins in separable parallel relationship.

59. The apparatus of Claim 58 wherein the first and second pins are pivotally mounted at the distal end of the extension.

60. The apparatus of Claim 58 further comprising means at the distal end of the extension for permanently isolating the lumen wherein the pins comprise electrodes which are connectable to an external radio frequency power supply.

61. The apparatus of Claim 56 wherein the shaft is less than 15mm in diameter.

62. The apparatus of Claim 55 wherein the isolation means are comprised of electrodes that are energized by radio frequency energy to thermally fuse the tissue to thereby isolate the tissue.

63. The apparatus of Claim 55 further including irrigation means wherein said irrigation means include a conductive fluid.

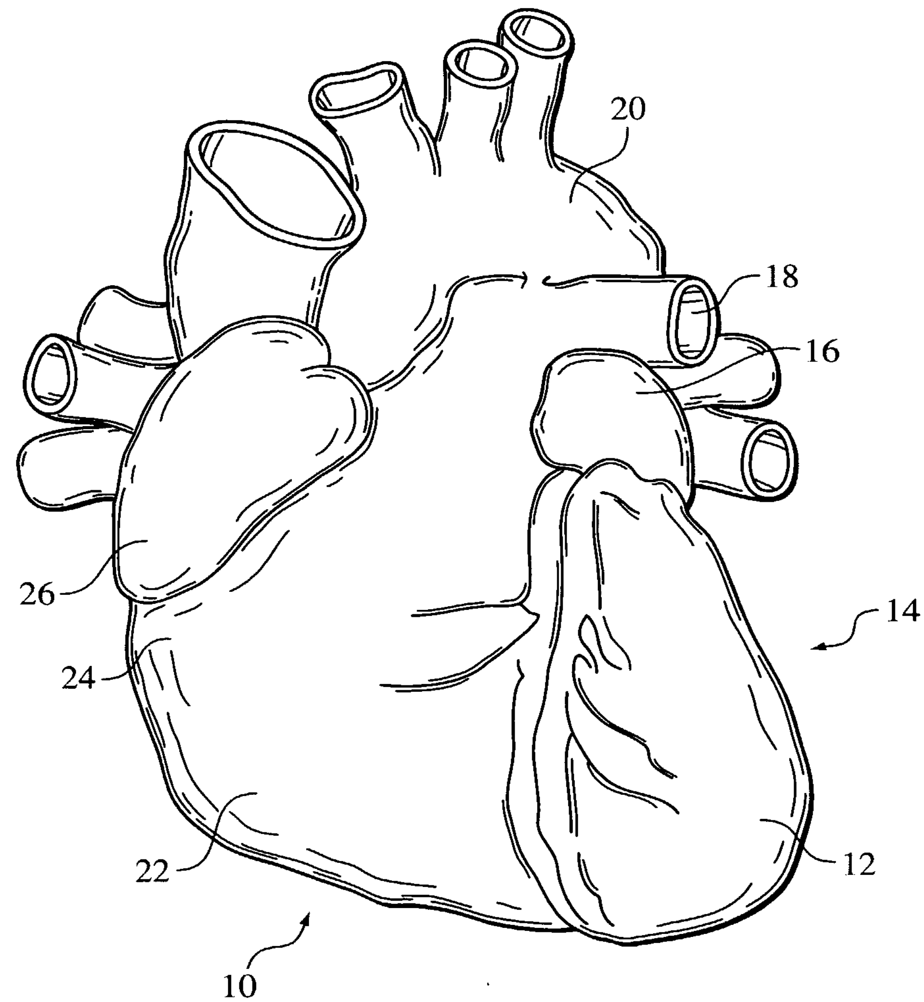


FIG. 1

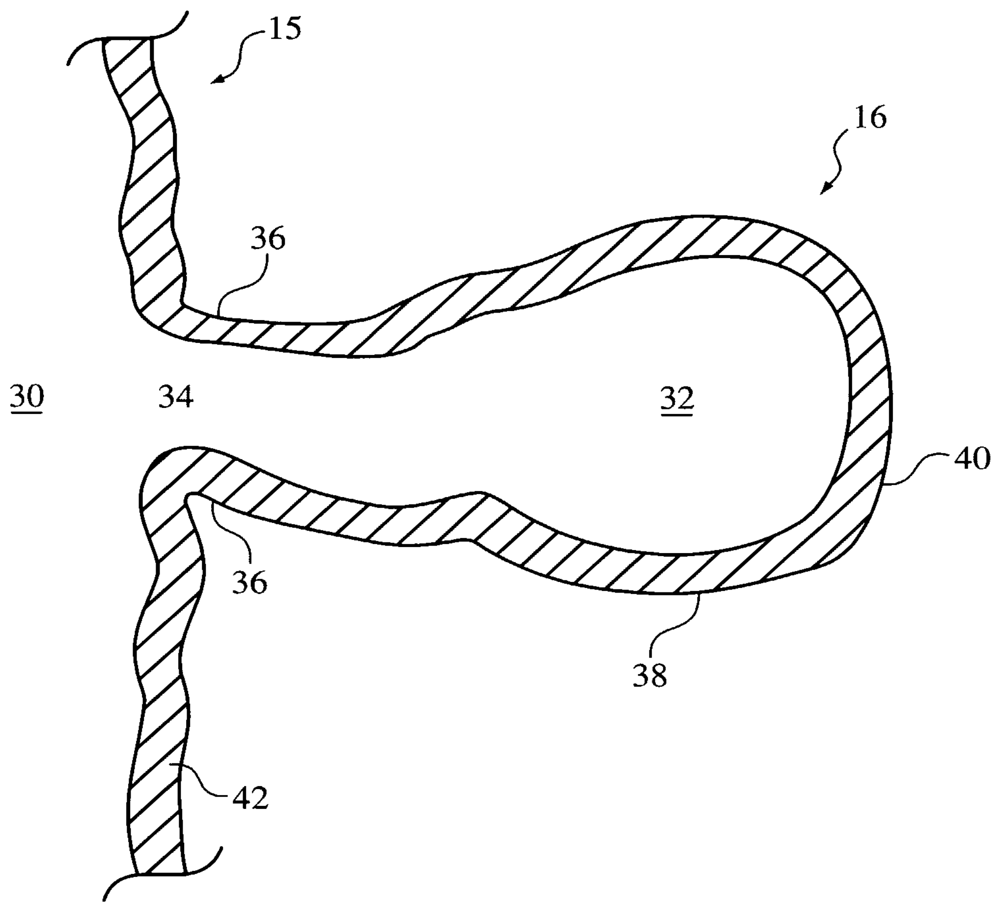


FIG. 2

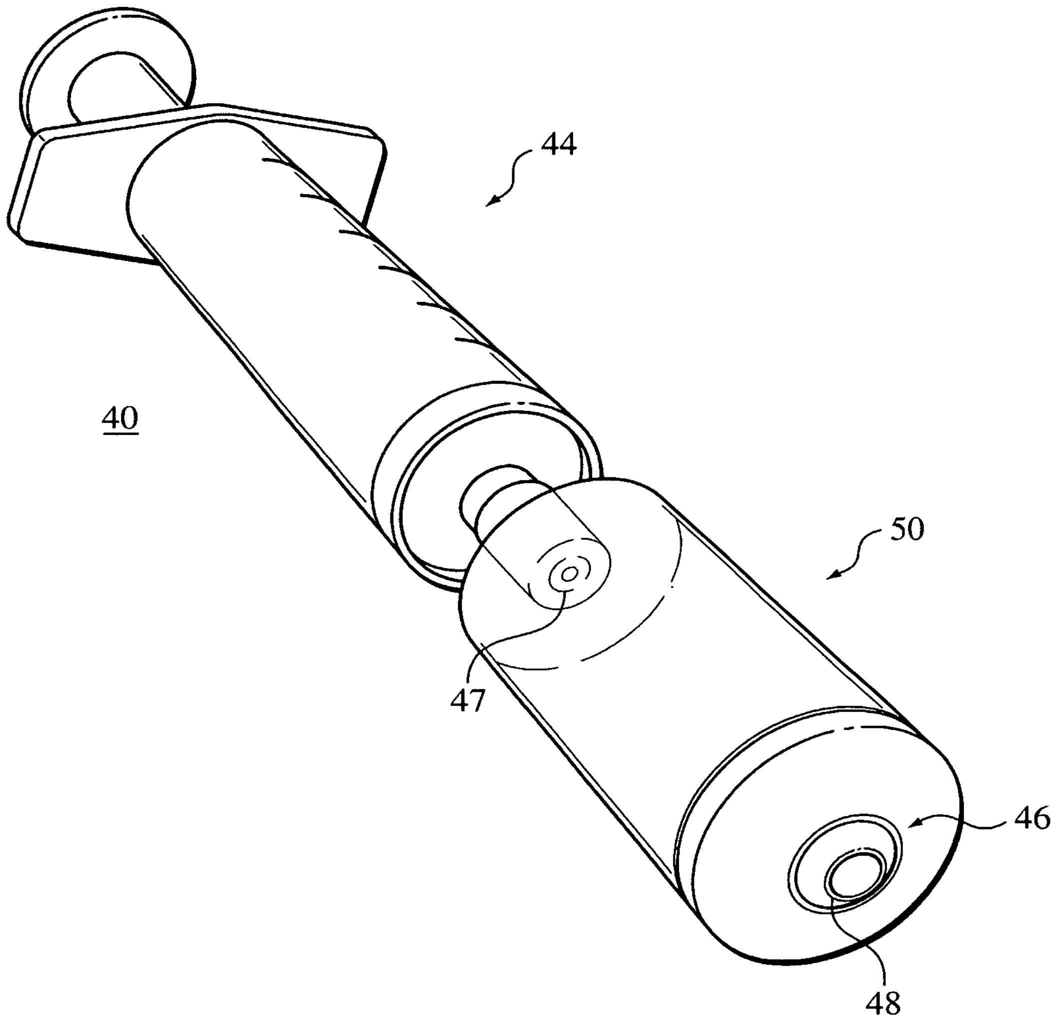


FIG. 3

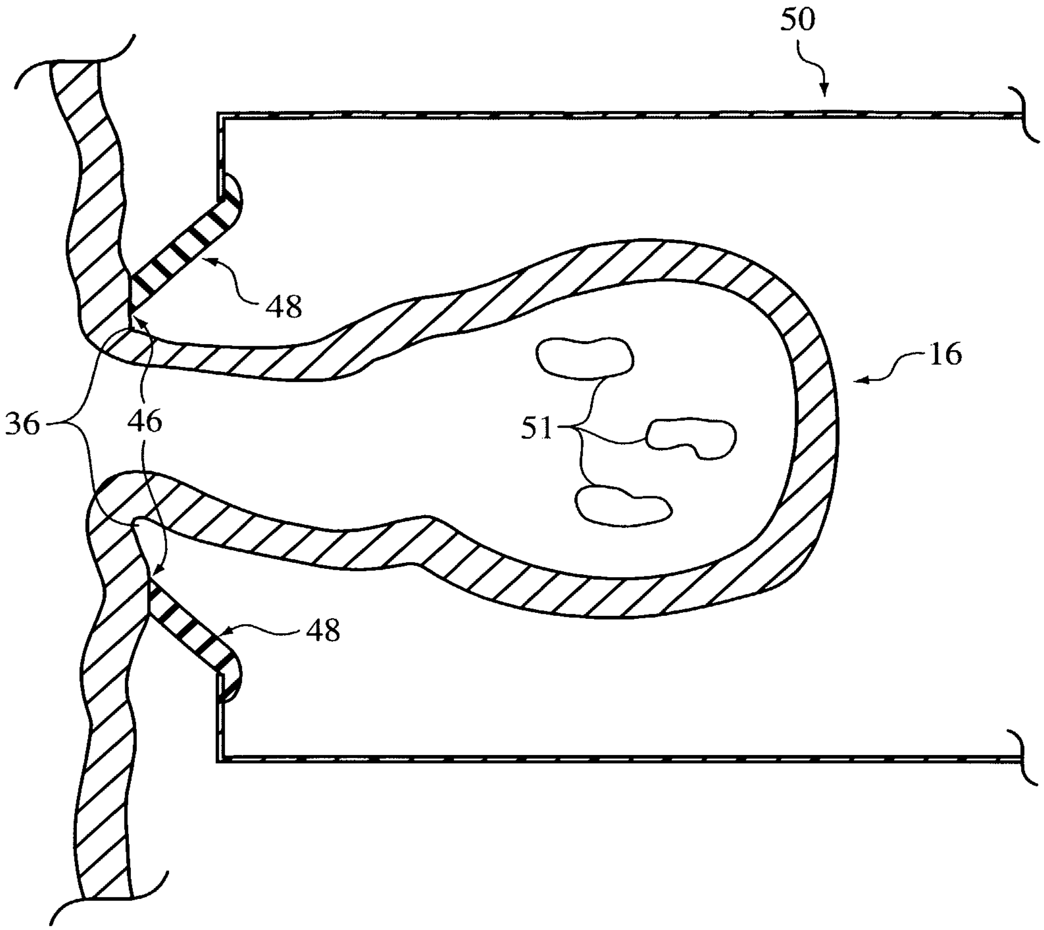
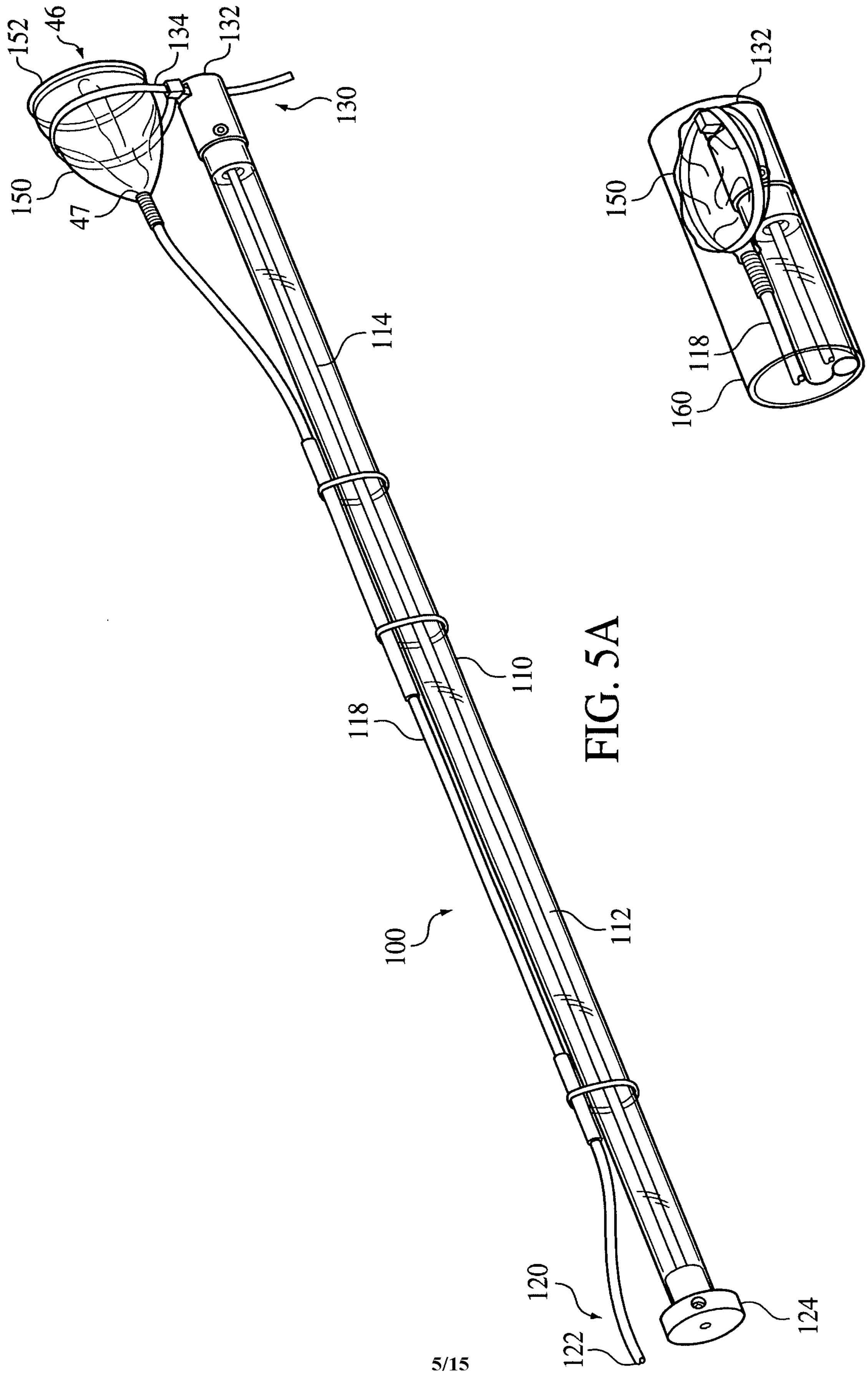


FIG. 4


152
46
134
132
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47
114
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100
112
120
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124
132
150
118
160

FIG. 5A

FIG. 5B

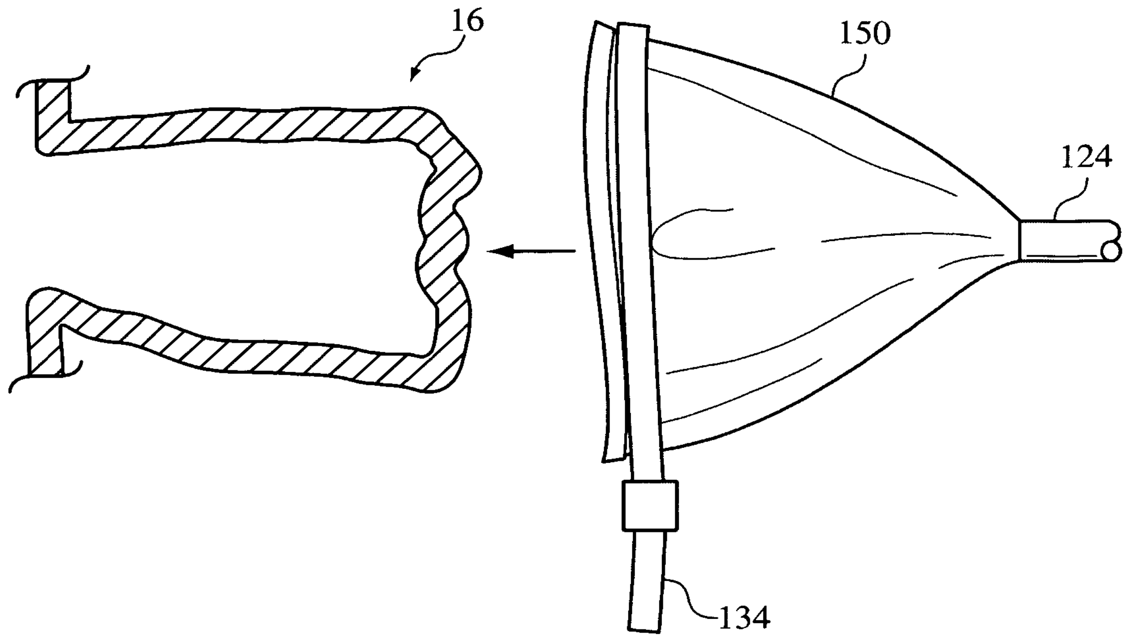

FIG. 6A

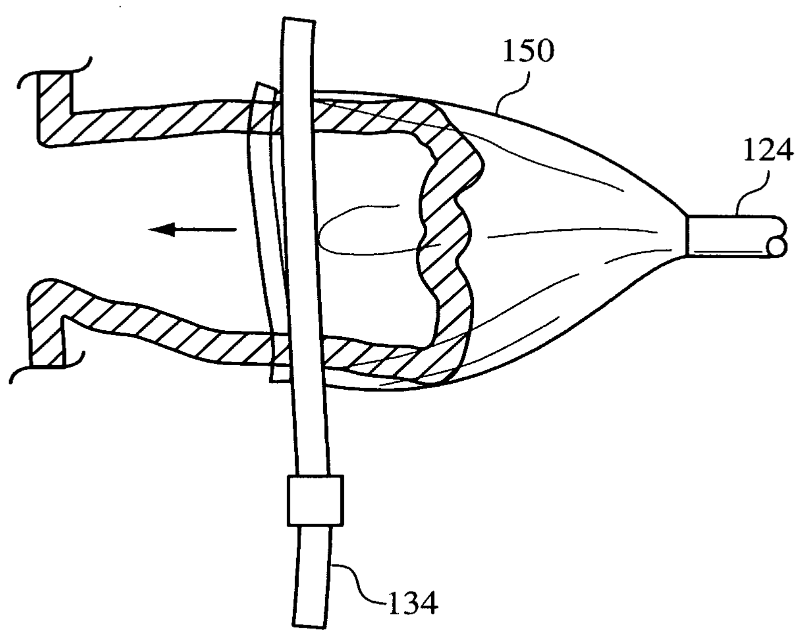

FIG. 6B

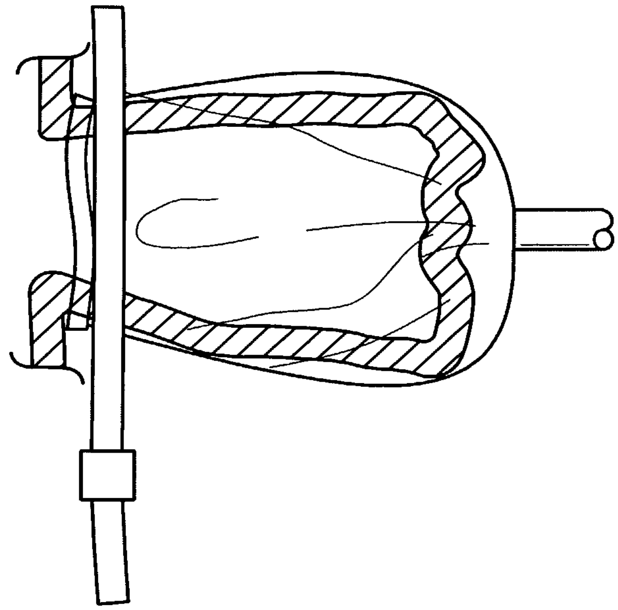

FIG. 6C

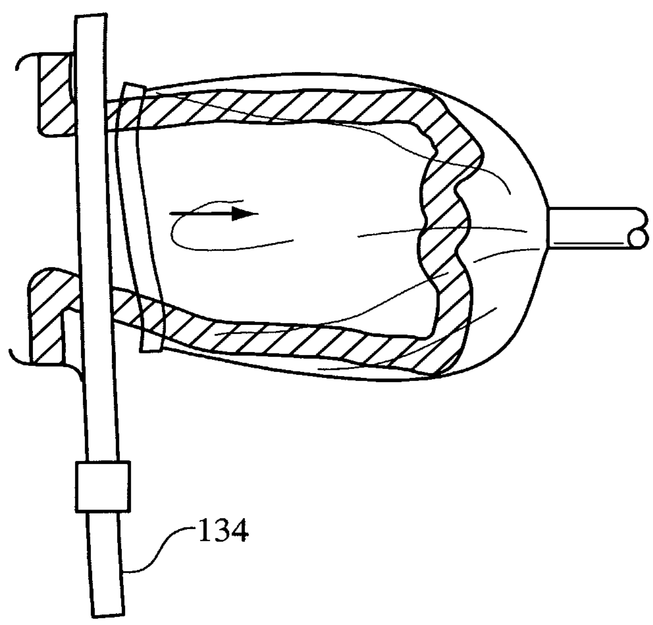

FIG. 6D

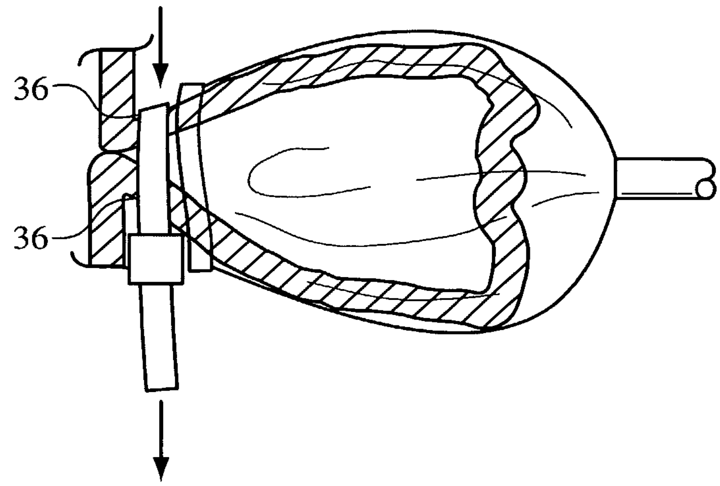

FIG. 6E

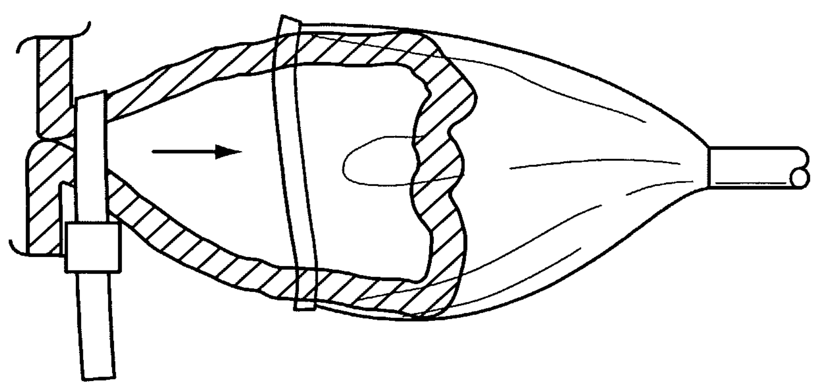

FIG. 6F

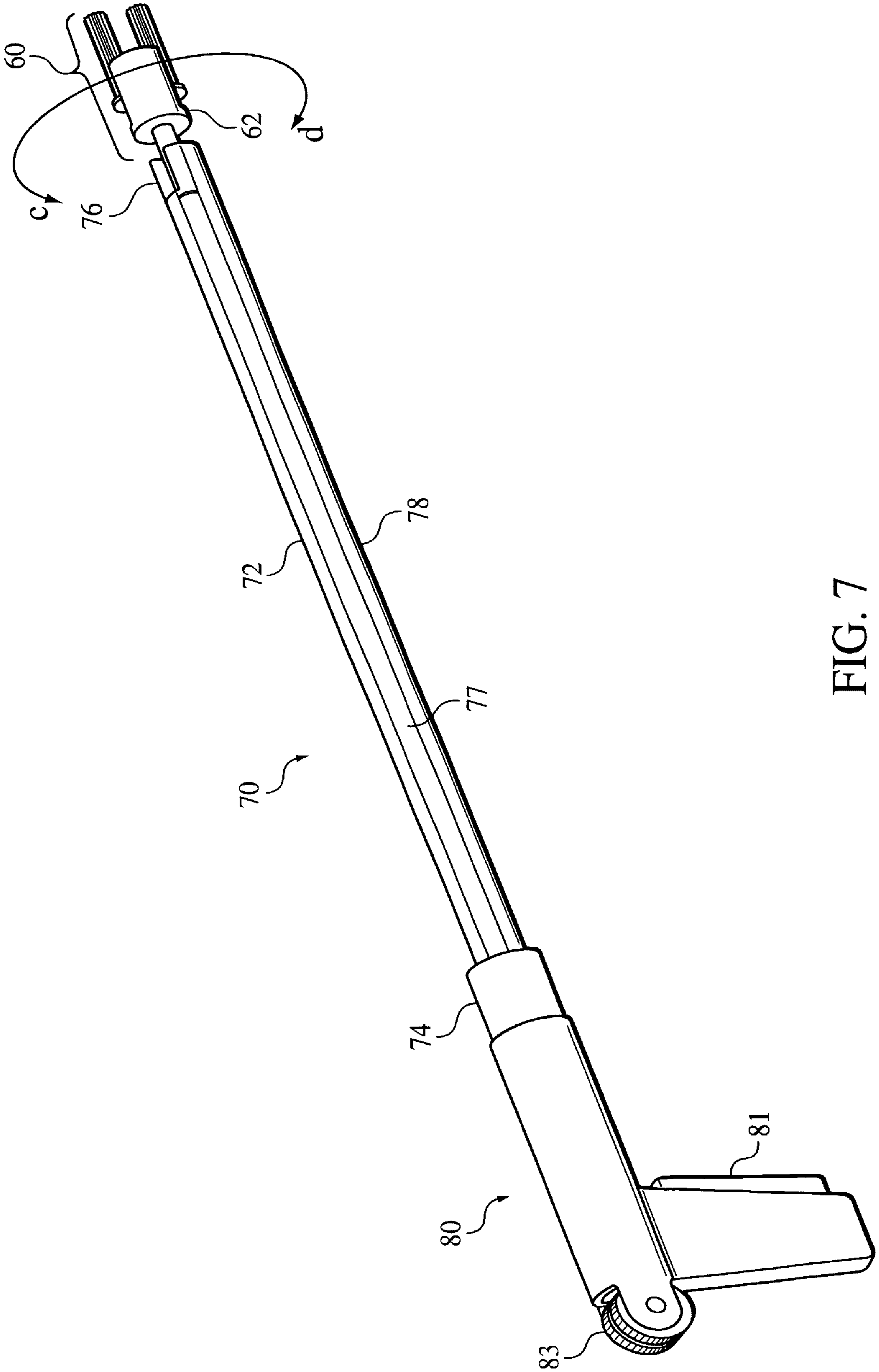

FIG. 7

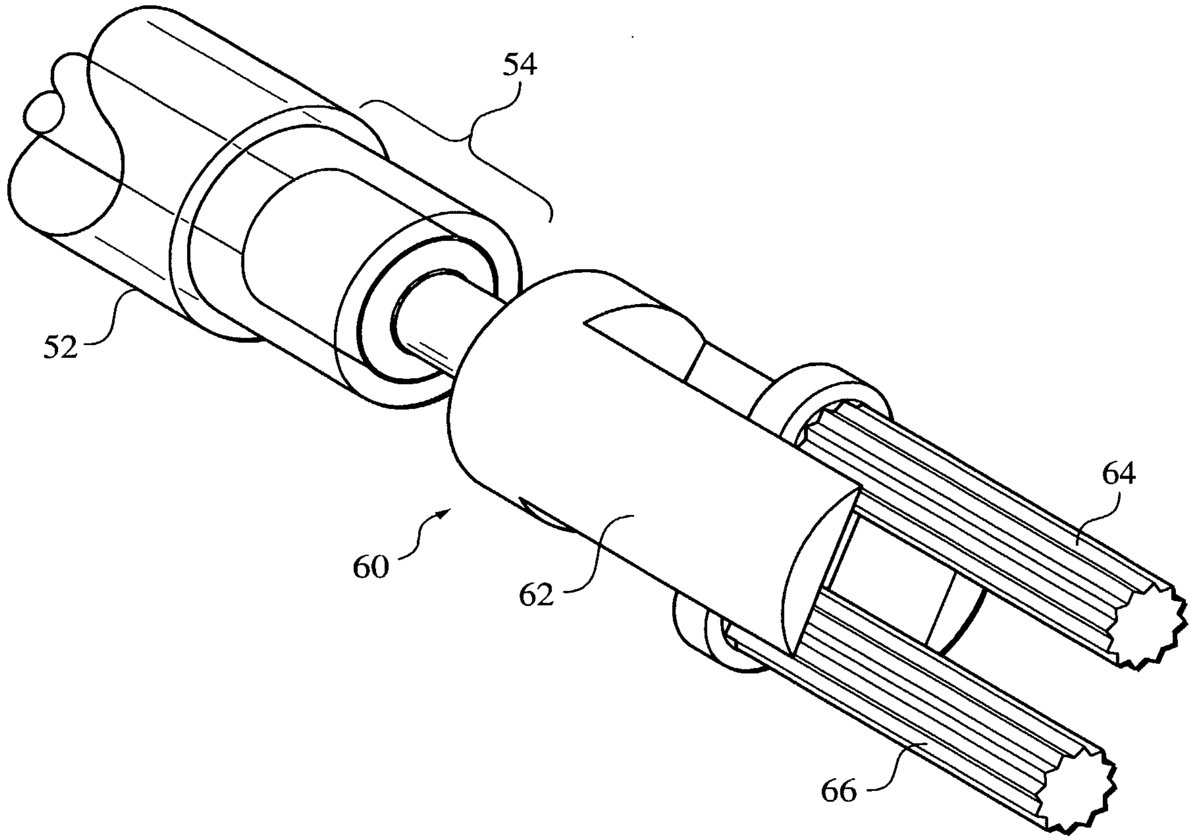

FIG. 8A

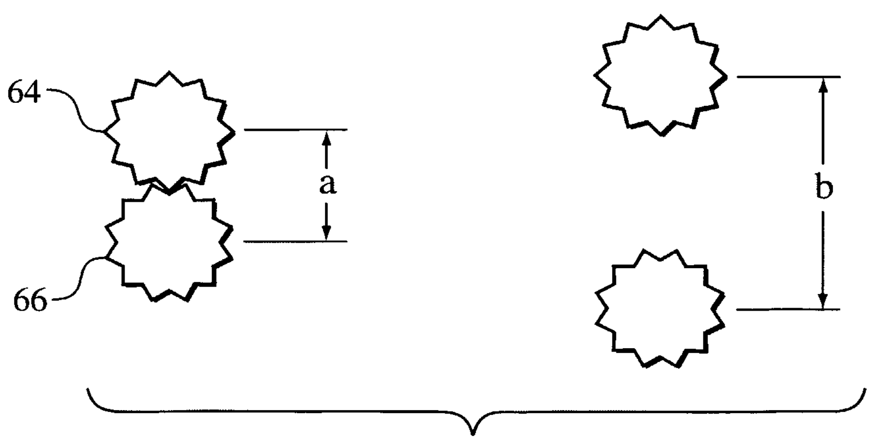

FIG. 8B

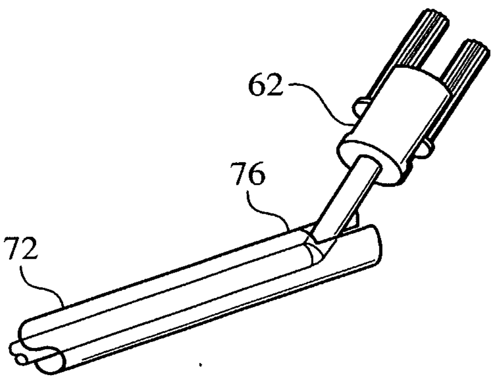

FIG. 9A

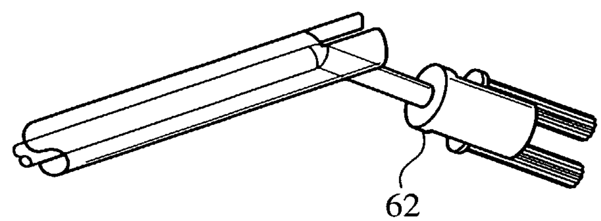

FIG. 9B

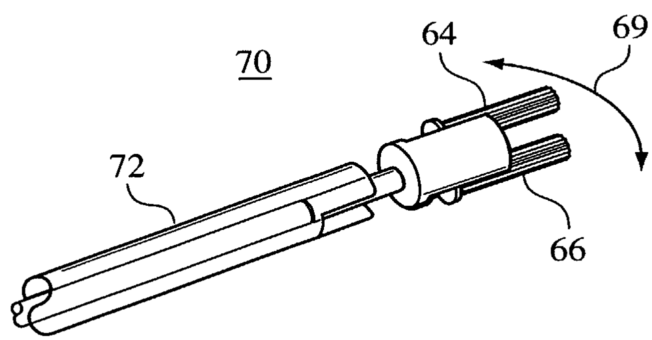

FIG. 9C

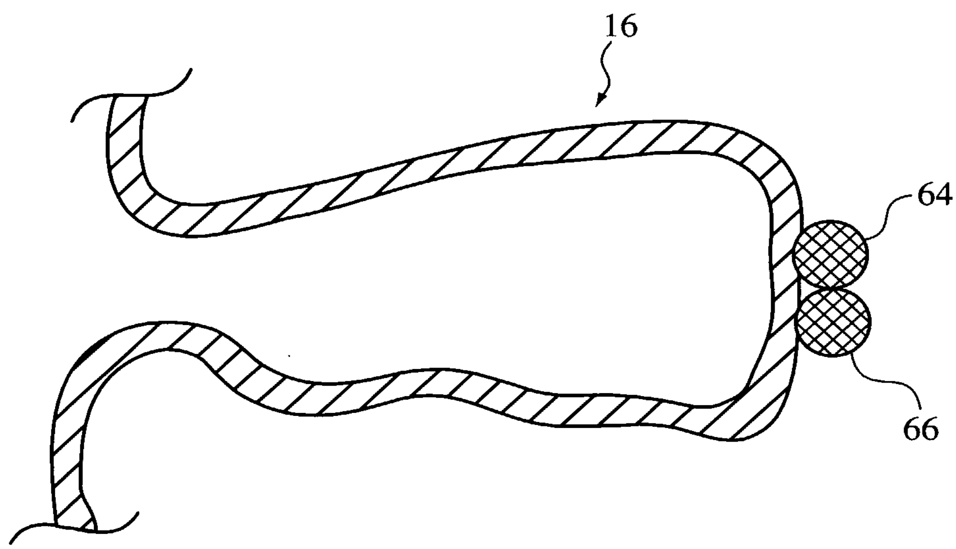

FIG. 10

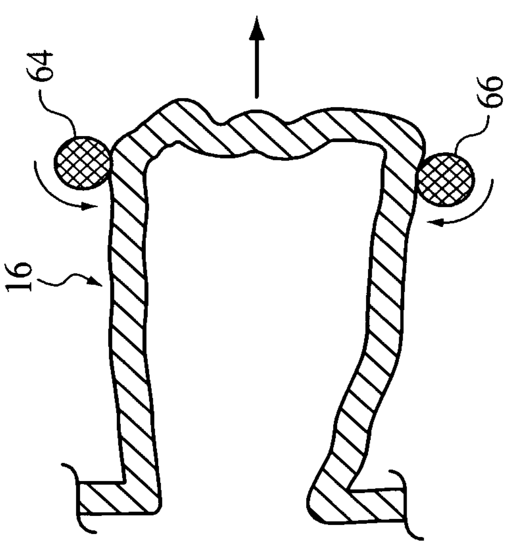

FIG. 11A

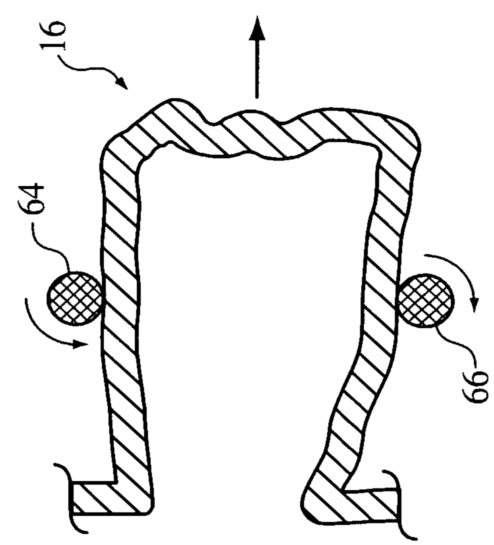

FIG. 11B

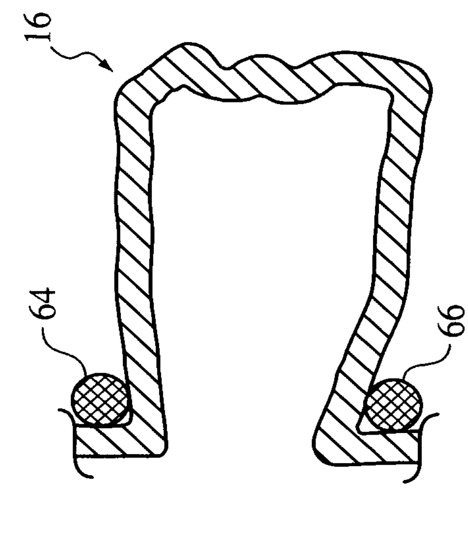

FIG. 11C

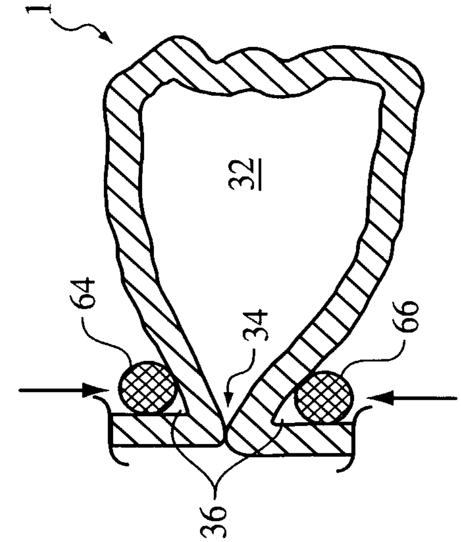

FIG. 11D

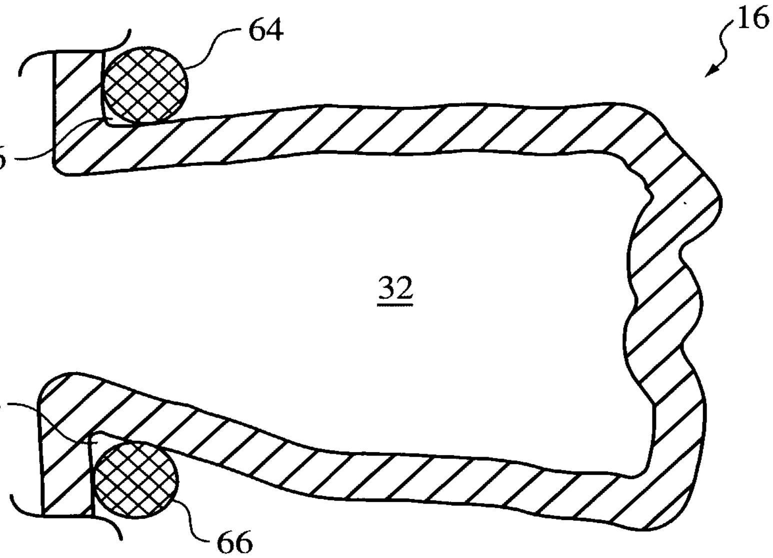

FIG. 12A

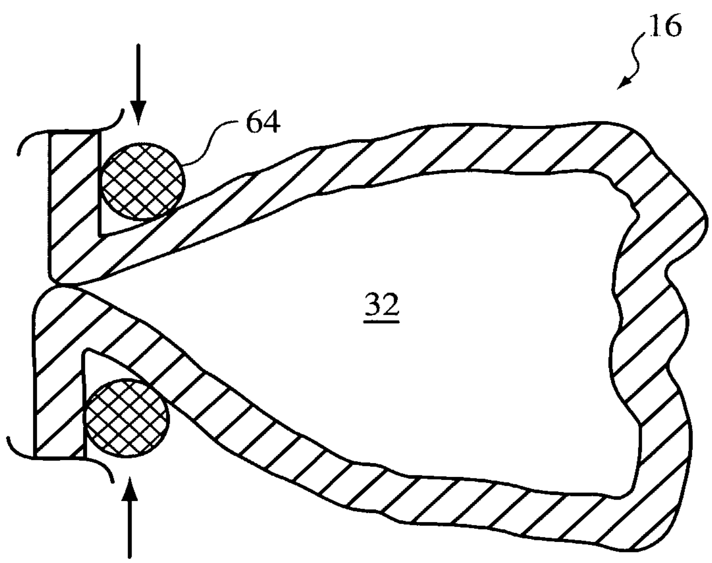

FIG. 12B

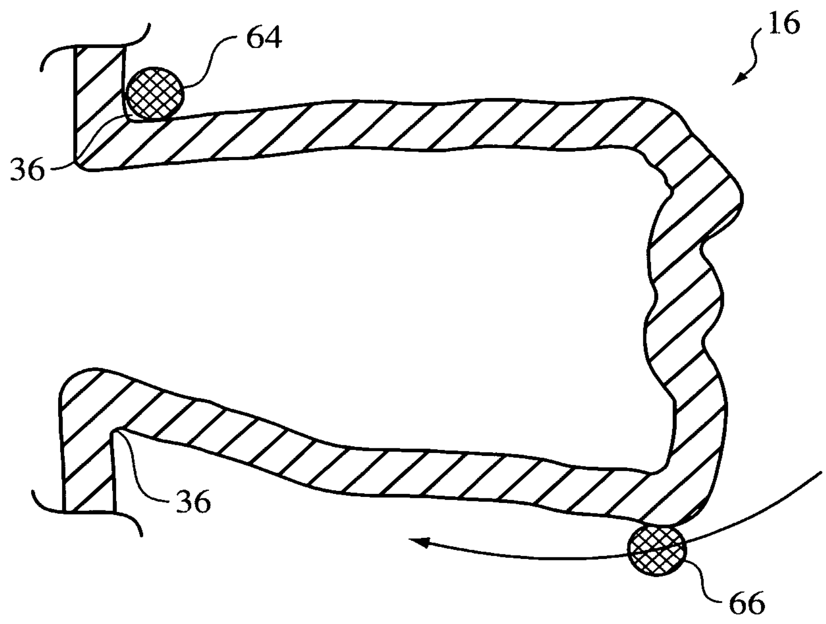

FIG. 13A

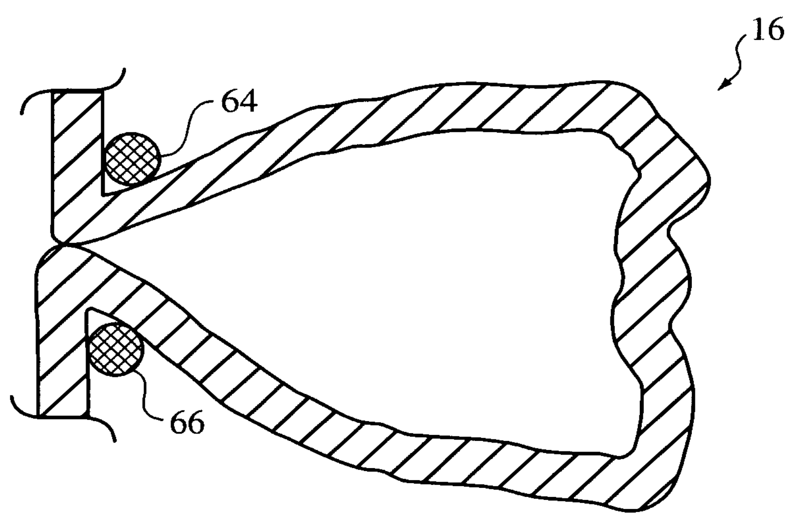

FIG. 13B